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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/990,497 | 11/21/2001 | Robert Waranis | RPS6096-US | 3407 |

7590 03/23/2004

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| EXAMINER | |
|---|---|
| JOYNES, ROBERT M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/990,497 | WARANIS ET AL. | |
| | Examiner | Art Unit | |
| | Robert M. Joynes | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-9 and 11-17* is/are pending in the application.

4a) Of the above claim(s) *2 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *December 9, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on December 9, 2003.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6, 9, 11, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5071643) in combination with Honour et al. (US 5529923) in combination with Veech (US 6020007).

Yu teaches a solvent system for acetaminophen comprising acetaminophen (Col. 5, lines 13-17), polyethylene glycol (Col. 4, line 41 – Col. 5, line 7; Col. 6, lines 23-35), as well as hydroxide ions, water, glycerin and polyvinyl pyrrolidone (Col. 7, lines 10-12). The system can also include suitable preservatives, stabilizing, or wetting agents and coloring substances (Col. 9, lines 29-32). The solvent system and solution are suitable

for soft gel encapsulation (Col. 10, lines 39-49). Yu does not expressly teach the inclusion of a lactate salt.

Honour teaches a solution composition in which buffering agent, tonicity agents and wetting agents such s a sodium lactate are used (Col. 8, lines 56-64). Honour teaches that sodium lactate is a known additive for solution formulations.

Yu and Honour do not expressly teach that the lactate salt is the l-lactate salt.

Veech teaches that the l-form of the salt is preferred in physiological conditions (Col. 2, lines 52-62).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add excipients such as preservatives, stabilizing, or wetting agents and coloring substances to a solution of acetaminophen. It would also have been obvious to a person of ordinary skill in the art to incorporate the l-form of the lactate salt in the solvent system

One of ordinary skill in the art would have been motivated to do this maintain a solution that is suitable and preferred in the physiological environment to which it is administered.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 4, 5, 7, 8, 12, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5071643) in combination with Honour et al. (US 5529923) in combination with Veech (US 6020007) in combination with Shelley et al.

(US 5505961). The teachings of Yu, Honour and Veech are discussed above. These references do not expressly teach the inclusion of potassium acetate.

Shelley teaches a clear solvent system similar to Yu's system but comprising potassium acetate (Col. 3, lines 21-27). Shelley teaches that the potassium acetate aids in the solubility of acetaminophen.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate potassium acetate into a solvent system solution with acetaminophen.

One of ordinary skill in the art would have been motivated to do this to aid in the solubility of the drug.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

Applicant's arguments filed December 9, 2003 have been fully considered but they are not persuasive. Applicants argue that the combination of the references is inappropriate because applicants allege the references are unrelated and technologically non-sensical. Further, applicants allege that the Examiner used improper hindsight and creativity to construct the rejections.

In response, the Examiner would like to point out that the primary reference is a solution of acetaminophen in capsule that can contain additional known solution type excipients such as wetting agents. The secondary reference is used to show that sodium lactate is a known wetting agent for solution formulations for delivery to the

body. Further, the tertiary reference is used to show a known idea of biochemistry that physiologically, the l-form is the favorable form of compounds to be delivered to the body. They are all liquid formulations. Therefore, it is the position of the Examiner that these references are related and NOT technologically non-sensical.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In view of the above arguments, the rejections are maintained.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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Robert M. Joynes